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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,291	04/07/2006	Timothy Tak Yip	035394-0292	2464
22428 7590 08/02/2010 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER LIN, JERRY	
			ART UNIT	PAPER NUMBER
			1631	
			MAIL DATE	DELIVERY MODE
			08/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,291

Applicant(s)

YIP ET AL.

Examiner

JERRY LIN

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) 1-83 and 88-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 84-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' arguments, filed May 19, 2010, have been fully considered and they are deemed to be persuasive in-part. The following rejections are reiterated. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 84-87 and biomarker WM-447 are under examination.

Claims 1-83 and 88-102 are withdrawn.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 84-87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary; (2)

the amount of direction presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; (8) the breadth of the claims. While each factor is not explicitly discussed, each factor has been considered and the relevant factors as discussed below.

The claims are drawn to a method of qualifying lung carcinoma status in a subject using one or more listed biomarkers embodied in a tangible computer-readable medium. However, specification recites that a detection of a pattern of these biomarkers allows the user to qualify lung carcinoma status (Specification, paragraphs 0006-0021). Only markers WM-446 and WM-447 are identified as markers capable of identifying lung cancer by themselves (paragraph 0011). The specification does not teach or show working examples of using the other biomarkers identifying lung carcinoma by themselves. Given that the art is unpredictable, one of skill in the art would have to perform undue experimentation in order to determine if any of these biomarkers are capable of identifying lung carcinoma by themselves.

In addition, because the biomarkers are listed in way that one of skill in the art could not verify if a detected protein was the same as a biomarker (see above), one of skill in the art must perform undue experimentation to determine if the detected protein was a biomarker of lung carcinoma.

Response to Arguments

3. Applicants have responded to this rejection by stating that while WM-446 and WM-447 are the only one node WCX markers used to determine lung cancer, Tables 1 and 2 on pages 14-16 of the specification expressly teaches the association of lung cancer with the presence of 2, 3, 4, 5, and 6 nodes. Thus, it appears that the specification does teach that there are sets of biomarkers which may be used to determined lung cancer. However, the instant claims recite one or more biomarkers is used to qualify lung carcinoma status, which is interpreted to mean that each biomarker may be taken singly to qualify lung carcinoma status. In contrast, the specification teaches that the biomarkers must be analyzed as particular sets to qualify lung carcinoma status. Thus, the specification does not teach one of skill in the art to use the claimed invention commensurate in scope with these claims. The examiner suggests amending the claims to reflect the particular sets of biomarkers which may be used to qualify lung carcinoma status as taught in the specification.

Declaration under 37 C.F.R. §1.132

4. The Declaration under 37 CFR 1.132 filed 5/19/2010 is sufficient to overcome the rejection of claims 84-87 based upon 35 U.S.C. §112 first and second paragraph as being indefinite and lacking written description. According the Declaration on paragraph 6, the combination of physical/chemical signatures provides sufficient information to infer identity in routine analysis. The applicants also state, on page 24 of the remarks, that the specification provides for molecular weights, metal ion affinity, and charge state,

which are sufficient to infer identity for purposes of analysis. Thus, these rejections are withdrawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:30-6:00pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Primary Examiner, Art Unit 1631
7/27/2010